MINUTES OF MEETING OF
AMBULATORY SURGICAL SERVICES TECHNICAL ADVISORY COMMITTEE
Department of Community Health, Division of Health Planning
2 Peachtree Street, 34th Floor Conference Room
Atlanta, Georgia 30303-3159
Tuesday, July 22, 2003 ■ 12:30 pm – 3:30 pm

William "Buck" Baker, Jr., M.D., Chair, Presiding

MEMBERS PRESENT
Tary Brown
Billy Carr
Kevin Chilvers
Daniel DeLoach, MD
J. Keener Lynn
Wallace McLeod, MD
Mark M. Mullin
Perry Mustian for Clay Campbell
William T. Richardson, FACHE
Temple Sellers, Esq. for Don E. Tomberlin, Sr.
Raymer Sale, Jr
William Silver, MD
Stephanie Simmons
Carol Zafiratos

MEMBERS ABSENT
Sylvia Caley, RN, JD
David Tatum
Kathy Floyd

GUESTS PRESENT
Todd Bacon, Northeast Georgia Health System
Jennifer Bach, Gill/Balsano Consulting
Armando Basarratte, Parker, Hudson, Rainer & Dobbs
Joy Davis, Rockdale Hospital
Jim Courtney, DHR/Office of Regulatory Services
Davis Dunbar, Piedmont Hospital
Ruby Durant, DHR/Office of Regulatory Services
Gayle Evans, Continuum Healthcare Consulting
Charles Hayslett, Georgia Alliance of Community Hospitals
Doug Holbrook, St. Joseph's Health System
Craig Kaiser, Jennings Ryan Kolb
Marvin Noles, Medical Center of Central Georgia
Michael Ochal, So. Orthopedics
Joe Parker, Georgia Hospital Association
Marty Rotter, DHR/Office of Regulatory Services
Tiffany Rupp, Gill/Balsano Consulting
Adam Severt, Georgia Hospital Association
Helen Sloat, Nelson Mullins
Kevin C. Taylor, Archbold Memorial Hospital
Monty Veazey, Georgia Alliance of Community Hospitals
L. Fressell Watkins, Powell Goldstein
Cam Grayson, Medical Association of Georgia

STAFF PRESENT
Valerie Hepburn
Jamillah McDaniel
Clyde Reese, III, Esq.
Stephanie Taylor

WELCOME AND INTRODUCTIONS

The meeting commenced at 12:40 pm. The Chair noted that Don Tomberlin and Clay Campbell were unable to attend today's meeting and are being represented by Temple Sellers and Perry Mustian, respectively.

REVIEW AND ADOPTION OF MAY 6TH & JUNE 24TH MEETING

Dr. Baker reminded members that the minutes of the meeting of May 6th were not adopted at the June 24th meeting because Mr. Richardson had asked Division staff to seek clarification about information that was presented by Clyde Reese regarding the purview of the committee. Valerie Hepburn indicated that she conferred with Mr. Reese about his statements to the TAC. Because Mr. Reese was present at the meeting, she asked him to respond to Mr. Richardson's concerns. Mr. Reese confirmed that the minutes of May 6th accurately represented his report to the TAC. Following this clarification, members formally adopted the minutes of the May 6th meeting. Dr. Baker then called for a motion to adopt the minutes of the June 24th meeting. Dr. McLeod recommended the following changes prior to adoption:

Under the heading of: Discussion of General Planning Standards and Possible Approaches/Indigent Care

(a) Insert the word "some" before the sentence that begins "members agreed that" ….
(b) Delete the following sentence "Members agreed that providers should be required to provide some level of indigent care". This sentence is duplicative of the preceding sentence.

Members agreed with the two recommended changes to the minutes of the June 24th meeting and unanimously approved and adopted the meeting minutes pending these changes.

REVIEW OF INFORMATION IN MEMBER PACKETS

Dr. Baker called on Valerie Hepburn to review the information sent to the TAC and included in member packets. Ms. Hepburn started by noting that followup data and other information were sent to members subsequent to the last meeting, including:

- Ambulatory Surgery Procedures and Rates of Procedures/Patient (provided by Division of Health Planning)
- Draft Standards, Office-Based Surgery, American College of Surgeons (provided by Dr. DeLoach)
- Two articles that address the office-based surgery problems experienced in Florida (provided by Carol Zafiratos, ORS):
    - Preventing Errors in The Outpatient Setting, *Health Affairs*, 21(4): 26-39, 2002
      And
    - Florida Bans Some Office-based Surgeries, *American Medical News*, September 4, 2000

She said that the articles provided by Ms. Zafiratos discussed licensure issues in office-based physician practices (mostly in the plastic surgery discipline) and did not provide any information that was indicative of CON or general quality of care issues in freestanding ambulatory surgery centers as was first thought.

Ms. Hepburn then reviewed the materials included in today's member packets including:

- Draft Ambulatory Surgery Guidelines for consideration by the TAC
- Letter from the Georgia Alliance of Community Hospitals (dated July 15, 2003)

- Letter from Georgia Association of Nurse Anesthetists (dated July 18, 2003)
- List of General Hospitals that meet the Safety Net Criteria (as of July 2003)
- Kevin Chilvers provided a list of List of Medicare CPT Codes for Ambulatory Surgery Centers (effective July 1, 2003) to TAC members.

Ms. Hepburn reminded TAC members that the draft guidelines which were mailed to members and which are included in member packets were crafted by Division staff to provide a broad framework to focus the committee's discussion and are in no way intended to represent a formal recommendation of the committee or the Health Strategies Council. The standards in this draft document were derived from several sources including, the Division's current planning documents, concepts gleaned from the TAC's previous meetings, other state planning documents, and standards and guidelines of appropriate national professional organizations and accrediting bodies. She said that following the committee's input, at today's meeting, this document would be revised and made available to the public for review and additional input. Additionally, a public forum is scheduled for Friday, August 8th in Macon, Georgia. Everyone is invited to attend this forum to provide the committee with verbal and/or written input. Following this public forum, this draft document would be sent back to the TAC for additional review and input.

Ms. Hepburn brought the committee's attention to correspondence in member packets, from the Alliance for Community Hospitals (Alliance) and the Georgia Association of Nurse Anesthetists (GANA). She indicated that the Alliance's correspondence outlines several issues, many of which are beyond the scope of the committee's work. GANA's correspondence addresses issues of scope of practice. The proposed rules do not address scope of practice for Nurse Anesthetists.

Ms. Hepburn said that the enclosed list of safety net hospitals are those that would qualify for this designation based on the 2002 survey cycle. A question was raised about the definition of "safety net" hospitals. Ms. Hepburn said that this definition was developed by the Short Stay General Hospital Technical Advisory Committee and is the one that is currently used in the Short Stay General Hospital rules. She reminded members that this list is not static and would be updated annually in conjunction with the Georgia Board for Physician Workforce, the Georgia Department of Human Resources and the Department of Community Health.

Ms. Hepburn thanked Kevin Chilvers for providing a list of Medicare-approved procedures that could be performed in ambulatory surgery centers. This list is effective as of July 1, 2003.

REVIEW AND REFINEMENT OF DRAFT OPTIONS AND GUIDELINES FOR AMBULATORY SURGERY SERVICES

Dr. Baker called on Ms. Hepburn to present the draft guidelines to the TAC. A question was asked about the origin of the Applicability standard. Ms. Hepburn indicated that this section has always existed but it has been expanded to specifically outline when these proposed guidelines would and would not apply. She said that while it is the mechanism through which CON applications are currently reviewed, it was felt that this delineation would provide greater clarity around the regulatory review process.

A question was asked about whether these rules would apply if a hospital-based ambulatory surgery center were to become a freestanding ambulatory surgery center. Ms. Hepburn indicated that if a center were no

longer under the auspices/licensure of the hospital, these rules would be triggered. She reiterated that these rules cover single-specialty and multi-specialty ambulatory CON-reviewed surgical centers only.

Members spent a considerable amount of time discussing ways to require physician-owned, single-specialty facilities to be reviewed under these rules. Ms. Hepburn continued to emphasize that physician-owned, single-specialty facilities are not regulated by the Department and are exempt from the CON review, pursuant to O.C.G. A. 31-6-2(14)(g)(iii). She said that while the Department can survey these facilities, they are under no obligation to respond to the surveys. It was further noted that such facilities are not required to be licensed to operate and usually only obtain a license from the Department of Human Resources to secure Medicare reimbursement. Ms. Hepburn said that any recommendations regarding physician-owned, single-specialty surgical facilities could be more appropriately addressed in the component plan under the section entitled "Goals, Objectives and Recommendations". These recommendations are presented to the Health Strategies Council and the Board of Community Health.

Ms. Hepburn started the review of the draft guidelines by seeking agreement from the committee on the approach that they would like to use to gain consensus around these standards. The committee agreed that an item-by-item, page-by-page process would work best. Members were asked to approve each standard addressed in the draft guidelines.

Applicability

The TAC unanimously agreed to accept standards numbered 1, 2, 3, and 5 as presented. Standards appearing below represent the identification of areas that resulted in further committee discussion, clarity and/or refinement.

4: *A party requesting designation as a physician-owned, single-specialty ambulatory surgery service that exceeds the capital expenditure threshold set forth in O.C.G.A. 31-6-2 (14) (G) (iii), and thus is not exempt from CON guidelines pursuant to this statutory provision, will be required to obtain a single specialty CON.*
Members inquired about how the thresholds are determined and the possibility of changing the threshold for physician-owned, single-specialty surgical providers. Ms. Hepburn indicated that the thresholds are calculated using the U. S. Census Bureau's annual Composite Fixed-Weighted Price (FWP) Index and are changed annually. An inflationary index is included in the methodology. Mr. Reese indicated that the current threshold for equipment is $711,225; construction $1,280,204 and for physician-owned, single-specialty CON exempt providers $ 1,390,470. It would require a statutory change to alter any of these thresholds.

6. *If an ambulatory surgery facility seeks to expand the number of ambulatory surgery operating rooms and the capital expenditure exceeds the CON threshold, the project will be reviewed under these rules.*
Members inquired as to how this standard would impact a hospital applicant. Mr. Reese indicated that hospital applicants would not be reviewed under these guidelines. If the applicant is a hospital seeking to increase the number of operating rooms and doing so triggers the capital threshold, the application would be reviewed under the General Considerations guidelines and not these service-specific rules. Only freestanding ambulatory surgery centers (single or multi-specialty centers) would be reviewed under these guidelines. Ambulatory surgery centers can add an operating room/s, without submitting a CON application, if they are able to do so without triggering the capital threshold. Once they have triggered the capital threshold, they would be required to submit a CON.

7. A replacement ambulatory surgery facility shall not be required to meet the need and adverse impact provisions of this chapter; but shall be required to submit an application and comply with all other provisions of the chapter.

Members asked why applicants seeking to replace their facilities would be exempt from addressing the need and adverse impact standards. Ms. Hepburn and Mr. Reese indicated that this standard was an attempt to allow some limited flexibility for existing providers to replace their practice should market conditions (i.e. skyrocketing rent) necessitate such a change. The current rules do not provide such flexibility and would require the submission of a new CON application. This replacement guideline, as initially proposed would allow the applicant to replace itself within 3 miles of the current location or if the replacement is beyond the 3-mile limit, the facility would have to be within the same county and serving the same patient population. The 3-mile radius provides a safeguard to ensure that the applicant ostensibly serves the same patient base. Applicants seeking to replace their facilities would be exempt from meeting the need and adverse impact statements because they were already existing providers in the county. They would be required to meet all other standards in the rules. Ms. Hepburn noted that this language parallels that of the Short Stay General Hospital Rules which were enacted earlier this year. The group discussed and amended the "replacement" definition later in the meeting.

Definitions

Definitions numbered 2, 4-10, 12, 13, and 17 were unanimously agreed upon by the TAC. Definitions appearing below represent the identification of areas that resulted in further committee discussion, clarity and/or refinement.

1. "Ambulatory surgery" means surgical procedures that include but are not limited to those recognized by the Centers for Medicare and Medicaid Services (CMS) and the American Medical Association as reimbursable ambulatory surgery procedures. Ambulatory surgery is provided only to patients who are admitted to a facility which offers ambulatory surgery and which does not admit patients for treatment that normally requires stays that exceed 24 hours and which does not provide accommodations for treatment of patients for periods of twenty-four hours or longer.

Ms. Hepburn indicated that there was an administrative error in the drafting of this definition. The word "overnight" should have remained in the definition. The Department sought to ensure that all state agency guidelines parallel each other for easy interpretation and compliance. The word "overnight" appears in the rules of the Department of Human Resources and should appear in the Department of Community Health's rules as follows:… "that normally requires stays that are overnight or exceed 24 hours". The committee spent some time discussing the insertion of the word "overnight" and agreed that it should remain in the rules.

3. "Ambulatory surgery operating room" means an operating or procedure room located either in a hospital or in an ambulatory surgery facility that is equipped to perform ambulatory surgical procedures that are invasive and/or manipulative and are identified as surgical procedures in the Current Procedural Terminology (CPT) coding of the AMA, and is constructed to meet the specifications and standards of the Office of Regulatory Services of the Department of Human Resources. The term operating room includes endoscopy and cystoscopy rooms and any rooms where scheduled procedures that are billed as surgical procedures are performed.

Ms. Hepburn explained that this definition seeks to clarify that endoscopy and cystoscopy rooms would be captured as operating rooms for the purpose of calculating the need methodology. The committee agreed that this clarification is appropriate and should be included in the rules. Also, Carol Zafiratos recommended that the words "Office of Regulatory Services" be removed from throughout this draft document. She clarified that the Department of Human Resources is referenced in state statute not the Office of Regulatory Services.

11. "Official inventory" means the inventory of all facilities performing or authorized to perform ambulatory surgery services maintained by the Department based on responses to the most recent Annual Hospital Questionnaire (AHQ) Surgical Services Addendum and Freestanding Ambulatory Surgery Services Survey and/or the most recent appropriate surveys, questionnaires and other available official data relating to the provision of ambulatory surgery services, and any ambulatory surgery facilities that have been approved for a CON but are not currently operational or were not operational during the most recent annual survey filing cycle.

Ms. Hepburn indicated that this standard has been changed to incorporate those facilities that have been approved but are not yet operational and were not operational during the survey cycle. Inclusion of these facilities would provide a more realistic inventory of existing resources. Committee members agreed to this change.

14. "Replacement" means new construction solely for the purpose of substituting another facility for an existing facility. New construction may be considered a replacement only if the replacement site is located within a three (3) mile radius or less from the ambulatory surgery facility being replaced or in the case of the facility proposing a replacement site beyond the three mile limit, if the replacement site is located within the same county and would serve the same patient population, based on patient origin by same county and would serve the same patient population, based on patient origin by zip code and payer mix, as the existing facility. Any new construction of an ambulatory surgery facility not meeting the definition for a replacement shall be required to obtain a CON as a new ASF.

Some TAC members thought that the 3-mile radius was too restrictive while other members felt that the definition was not restrictive enough and should require additional constraints. After considerable discussion, members unanimously recommended that the following language be deleted from this standard: "or less from the ambulatory surgery facility being replaced or in the case of the facility proposing a replacement site beyond the three mile limit, if the replacement site is located within the same county and would serve the same patient population, based on patient origin by same county and would serve the same patient population, based on patient origin by zip code and payer mix, as the existing facility".

15."Safety net hospital" is defined as a hospital that meets at least two (2) of following criteria:

(a) the hospital is a children's or a teaching hospital;
(b) the hospital is designated by the Department of Human Resources as a trauma center;
(c) Medicaid and PeachCare inpatients admissions constitute 20% or more of the total hospital inpatients admissions;
(d) Uncompensated charges for indigent patients constitute 6% or more of hospital adjusted gross revenue; or
(e) Uncompensated charges for indigent and charity patients constitute 10% or more of hospital adjusted gross revenue.

Members again asked about the designation of safety net hospitals. Ms. Hepburn further elaborated on this definition by indicating that the state has an interest in protecting teaching and trauma designated hospitals because these facilities are vital to the state's health care system. Teaching hospitals provide training opportunities for the state's healthcare workforce, they provide a disproportionate amount of care to the state's poor and uninsured population and they provide highly specialized clinical services. Hospitals designated as trauma facilities require huge amounts of resources in order to maintain this designation and to provide the highest quality of care. Children's hospitals and providers of substantial uncompensated and public insurance services are considered safety net hospitals.

Bill Richardson asked about the possibility of including "sole community rural hospitals" or "rural referral hospitals" as safety net hospitals. Ms. Hepburn indicated that the definition should be consistent throughout all of the Department's rules. This definition is the same as that which appears in the Short Stay General Hospital Rules which were recently updated. Members agreed to retain this definition.

16. "Single specialty ambulatory surgery service" means an ambulatory surgery facility meeting the definition in Number 2 and offering surgery in one of the following specialties:

colon and rectal surgery,
dentistry/oral surgery,
dermatology,
gastroenterology,
obstetrics/gynecology,
ophthalmology,
orthopedics,
otolaryngology,
neurology,
pain management/anesthesiology,
physical medicine and rehabilitation,
plastic surgery,
podiatry,
pulmonary medicine,
urology, or
vascular

as evidenced by board eligibility or certification in the specialty.

Ms. Hepburn mentioned that this definition was augmented to include the areas that appear in bold caption. These single-specialty areas were added given the strength of information from other states, materials from several associations, consideration by the Department and committee member input. Those specialties that appear in bold are those that were added to this draft document for TAC consideration. Ms. Hepburn further noted that this list would be used to provide guidance to the Department in the identification of single specialties for the issuance of Letters of NonReviewability (LNRs) to physician-owned, single specialty providers (CON exempt providers).

Bill Richardson made a motion, seconded by Billy Carr to remove vascular surgery from this list of single specialties. 4 members voted to remove it; 4 members abstained; 6 members (including chair) voted to keep vascular surgery as a single specialty on the proposed list. (One member left the meeting prior to this vote). The motion failed and "vascular" remained on the list of single specialties.

Minimum Facility Size

There were no recommended changes to this standard.

Need Methodology

Ms. Hepburn indicated that this methodology is the same as the current methodology. The major difference is that all facilities that have been approved but are not yet operational will be added to the inventory. This would allow a more accurate depiction of available resources. Mark Mullin indicated that he would like to see some data that justifies the 90 minutes (to justify the average time for ambulatory surgery procedures) in this methodology. Ms. Hepburn provided a copy of the Ambulatory Surgery Guidelines that are issued by CMS (416.65) to Mr. Mullin for reference. This document states that ambulatory surgical procedures are limited to those that do not generally exceed a total of 90 minutes

operating time and if the covered surgical procedures require anesthesia, the anesthesia must be 90 minutes or less in duration. Staff agreed to provide additional information to the TAC.

Exception to Need

Ms. Hepburn indicated that the Department has included an Exception to Need standard in almost all of its rules. The Department believes that there are some instances where the numerical need does not adequately reflect the need for services. The examples that are provided are an attempt to illustrate the exception standards of cost, quality and access. The TAC discussed the exceptions and Ms. Hepburn indicated that some tightening of the language would be needed. A motion to accept these standards was made by Dr. McLeod, seconded by Mark Mullin. Motion carried.

Adverse Impact

Ms. Hepburn indicated that all applicants seeking new or expanded ambulatory surgery services would be required to address the impact of any proposed service on existing services in the planning area. Both components of the adverse impact criteria must be met when examining this standard. First, the aggregate utilization rate of all existing and approved ambulatory surgery services must be 80% or above before an application would be reviewed and an applicant must demonstrate that safety net hospitals in the planning areas are not negatively impacted. Members voted to approve these standards as written.

Financial Accessibility

Ms. Hepburn indicated that the Department is fully committed to the standard of financial access and the provision of care to the state's indigent, low-income and uninsured population. This standard is apart of all of the Department's current rules. Members voted to approve this standard as written.

Favorable Consideration

Ms. Hepburn indicated that this standard is triggered only in instances where there are competing and comparable applications. This standard addresses the concept of accessibility to appropriate services. The Department will give special consideration, when considering competing applications, to the applicant that has a stronger record of serving indigent and charity care patients and providing a higher percentage of services to Medicare, Medicaid, and PeachCare patients. Members voted to approve this standard as written.

Quality of Care

Ms. Hepburn indicated that this section encapsulates existing rules, rules of the American Society of Anesthesiologists, American College of Surgeons (ACS), among others. She said that there was a need to further strengthen the Department's rules to ensure that providers are held to providing the highest quality of care. Dr. DeLoach expressed concern that some of the proposed language does not parallel that of the ACS. He agreed to work with Division staff to finetune this section of the draft rules prior to dissemination to the public.

Continuity of Care, Viability and Cost Containment

Mark Mullin asked why providers are not required to provide "charge data" on the surveys or collected on the patient discharge system (PDS). Ms. Hepburn indicated that charge data from the PDS has been viewed as proprietary information. She indicated that the Department could readily access charge data from the Division of Medical Assistance and State Health Benefit plans and other sources. Mr. Mullin indicated that he would confer with the Georgia Hospital Association subcommittee that he chairs to get some feedback about when "charge data" from PDS might be used. There were no recommended changes to this standard.

Data and Reporting

There were no recommended changes to this standard.

NEXT STEPS AND UPCOMING MEETINGS

Dr. Baker reminded everyone that the Public Forum is scheduled for Friday, August 8th at Coliseum Medical Center in Macon, Georgia. It is scheduled to begin at 10:00 am. Information would be mailed to committee members and posted on the Department's website under the Public Meetings section. Because full TAC membership is not required for the public forum, Dr. Baker solicited volunteers from the committee to attend the public forum. The following persons volunteered to serve on this subcommittee:

- Clay Campbell (by proxy)
- Billy Carr
- Wallace McLeod, MD
- Mark Mullin

Dr. Baker also reminded members that the next TAC meeting is scheduled for Tuesday, August 26th at 12:30 pm at 2 Peachtree Street, 34th Floor Conference Room.

PUBLIC COMMENTS

No one indicated the desire to speak.

ADJOURNMENT

There being no further business, the meeting adjourned at 3:35pm.

Minutes taken on behalf of chair by Stephanie Taylor and Valerie Hepburn.

Respectfully Submitted,

William "Buck" Baker, Jr., MD, Chair